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Dockets Management Branch (HFA-305)
Docket No.s 98N-1230 and 98.045N2
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Salmonella Enteritidis in Eggs - Notice of Proposed Rulemaking

The Association of Food and Drug Officials' Board of Directors, hereinafter referred to as AFDO, is pleased to offer comments on the Food and Drug Administration's (FDA) and Food Safety and Inspection Services's (FSIS) notice of proposed rulemaking relative to Salmonella Enteritidis (Se) in eggs, including safe handling instructions for shell eggs, coordination of the regulation of shell eggs, and other ways to reduce or eliminate Se in shell eggs.

AFDO is a 103 year old organization that represents federal, state, and local government regulatory officials, many of whom are now actively involved with food safety efforts focusing on the safety of eggs. It is clear to AFDO that these officials believe that government intervention into production, processing, storage, shipping and distribution of eggs is the appropriate response needed at the present time.

Control of Salmonella Enteritidis (Se) in eggs must incorporate a broad based, multi-pronged approach that begins with intervention at the production level. A reduction in the level of SE contaminated eggs and corresponding incidences of Salmonellosis cannot be expected unless introduction of the microbe at the production level is severely restricted. Consequently, such production level restriction practices must include principles based on sanitary standard operating procedures (SSOPs), good agricultural practices/good manufacturing practices (GAPs/GMPs), hazard analysis and critical control point (HACCP) concepts, and/or other interventions that may be developed, such as feeds that control or eliminate Se within flocks or through competitive exclusion. AFDO believes that SSOPs in conjunction with GAPs/GMPs will present the most feasible intervention strategy for all producers, regardless of size; HACCP is certainly an appropriate option at the production level with major producers but mandatory HACCP may create cost barriers that critically hamper smaller producers' ability to survive. In conjunction with programs that incorporate

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SSOPs and GAPS/GMPs, a nationwide mandatory flock monitoring program, amply funded by the Federal Government and similar to the system employed by Pennsylvania, must be implemented to obtain firsthand data on Se strains and to assure that suspect eggs are removed or diverted from the fresh market.

Strategies developed to control post-production growth of Se must be consistent with other requirements that are employed throughout the processing, storage, shipping and distribution chains. Temperature requirements, SSOPs and GMPs employed within the egg industry should be based on the same principles that are incorporated for other potentially hazardous, refrigerated foods. AFDO previously commented on FDA's notice, Guidance on Labeling of Foods That Need Refrigeration by Consumers, Docket No. 96D-0513; additionally, AFDO has developed a position paper with respect to FDA's and FSIS's advance notice of proposed rulemaking on Transportation and Storage Requirements for Potentially Hazardous Foods, Docket No. 95-049A. AFDO believes that any final regulations on Se in eggs should uniformly incorporate provisions as identified in our previous comments and position paper.

AFDO is not convinced that a lengthy statement regarding safe handling instructions for shell eggs is appropriate, since previous focus group studies FDA has cited for other foods indicate that consumers generally do not pay much attention to such statements, particularly if they are lengthy. FDA received similar comments regarding the length of the original versions of some of the proposed health claim statements developed under the Nutrition Labeling and Education Act. On the other hand, AFDO fully supports the use of the statement "**IMPORTANT, Must be Kept Refrigerated**", or, "**IMPORTANT: Must be Kept Refrigerated for Safety.**" on retail packaging for eggs. AFDO also believes that this labeling is appropriate for institutional packs of shell eggs. If FDA determines that additional safe handling instructions are needed, similar to those currently used on retail packages of ground meat, such instructions should be **in addition** to the above bold faced labeling. AFDO does not believe that warning statements per se should be expected to achieve any significant reduction in the numbers of foodborne illnesses associated with Se.

AFDO also supports the use of a uniform coding system that will facilitate traceback and recall activities, and a date coding system that is readily recognizable and meaningful to consumers. However, unless there is a specific regulatory requirement for eggs to have an "expiration date", AFDO believes that the exclusion of voluntary expiration dating cannot be considered a violation of 403 (a) of the Federal Act. AFDO believes that FDA should strongly consider such a coding system in addition to safe handling instructions.



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Uniform temperature requirements are a necessary Se control parameter and should be designed for consistency throughout the useable life of eggs. Except during processing operations where the temperature is expected to be elevated (i.e. washing and packing), eggs should be maintained at an ambient temperature of 45° F or less. Additionally, AFDO believes that rapid cooling methods that reduce the internal temperature of eggs to 45° F or less within a reasonably short period of time must be incorporated following washing and packing operations and prior to shipping or storage. Such requirements may necessitate research and development of improved cooling and packing methods. Since USDA and FDA are both encouraging nationwide adoption of the Food Code, and since AFDO has endorsed the 1997 edition of the Food Code and is also promoting its adoption by states and localities, AFDO believes that, unless FDA can show that no additional reduction in the growth of Se will occur if shell eggs are stored at the proposed 45 degrees F rather than at 41 degrees F., serious consideration should be given to a requirement of 41° F ambient temperature during storage, shipping and distribution of eggs to promote consistency of temperature requirements within the Food Code.

AFDO also believes there should be no exemptions from the temperature requirements. USDA's regulations exempt certain small producers, and there could be confusion among these producers, as well as farmer's markets, regarding the refrigeration requirements. AFDO supports across-the-board application of all food safety requirements for shell eggs, including the refrigeration/temperature requirements.

Similarly, AFDO believes that certain sections of the Food Code will have to be revised in order to be consistent with this proposed regulation. For instance, the Food Code does not exempt shell eggs, treated to destroy all Se, from refrigeration.

Although AFDO agrees with the principle of uniformity (or motto is "uniformity through cooperation and communication"), we do not support federal preemption unless there is a significant public health issue where science and risk assessment show that current systems are not working. AFDO agrees that the temperature for shell eggs should be uniform as long as states are free to enforce equivalent state requirements under state laws and regulations and as long as the preemption is a *minimum standard*. Current language in the proposed rule does not appear to provide for equivalent state statutes.

AFDO believes that states should be permitted to require lower temperatures if they believe their citizens will be better protected by a lower minimum temperature, such as 41 degrees F, particularly if the science on this issue is still out.



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While AFDO supports the requirements for refrigeration of shell eggs from farm through retail sale to consumers, along with appropriate label information regarding safe handling, AFDO does not believe that the agency has justified the rationale for use of the Public Health Services Act for enforcement of communicable disease quarantines to preempt state and local jurisdictions based on the facts provided in the preamble to the proposed regulation.

The Se problem surfaced in 1988 and was addressed in numerous hearings since that time. As a result many intervention strategies have been suggested and implemented. In 1991 the FDA identified shell eggs as potentially hazardous foods, advising state and local jurisdictions of this interpretation of the earlier versions of the model retail codes. Since 1995, and particularly after the 1997 version of the Food Code, states began adopting the Food Code with its more stringent temperature requirements for potentially hazardous foods. Simultaneously, the USDA implemented new Egg Product Improvement Act procedures to reduce the probability that flocks would become infected. From 1996 through 1998, epidemiological data developed through FoodNet show a **44 percent reduction** in human Se isolates per 100,000 population. The Salmonella Enteritidis Risk Assessment Report in June 1998 indicates that the implementation of 45 degree F. ambient air temperature requirement from flock to retail will result in an additional eight percent reduction in human illness. Clearly the 44 percent reduction in Se isolates since 1996 is a reflection of the implementation of multiple intervention strategies beginning at the farm and continuing to the table.

One of these strategies is a strong consumer education campaign in egg preparation safety. Using the Risk Assessment Report information, a decrease in reported human illnesses of approximately 4,000 can be expected. Part of that reduction is already realized under current state and local enforcement of the egg refrigeration requirement. AFDO's understanding is that 38 states have already adopted a 45 degree F. ambient air temperature requirement for shell eggs. The Report also indicates an expected contamination rate of 5/100,000 Se positive eggs. While these figures do provide a basis for regulation, they do not reflect a significant and unaddressed problem necessitating preemption of state and local regulatory authorities which are clearly having an impact on lower the incidence of Se. **Along with AFDO, FDA and USDA should instead devote their resources toward the adoption of the Food Code by state and local jurisdictions.** AFDO is a consensus builder, and we are actively involved in efforts to create uniformity throughout the country without resorting to preemption.



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Further, AFDO would not agree to preemption of state administrative procedures. If the object of this proposed regulation is to protect the public from unsafe eggs, the states and local authorities should be free to implement their own procedures that will accomplish the same end result - elimination of unsafe eggs from commercial channels. Most states have detention authority, as well as administrative procedures to assure that not only are unsafe foods removed promptly from distribution, but that the owner of the eggs is given ample opportunity to plead their case before the courts or an administrative law judge. Therefore, AFDO would object to any proposal to preempt the states in procedural matters. AFDO provided FDA similar comments during the development of the Food Code. AFDO's reading of 101.17(h) leads us to believe that state administrative procedures are **not** specifically preempted but asks for a clarification if this issue.

AFDO does not agree with the statement found in 101.17(h)(7) which indicates that FDA wishes to preempt state actions ("....until FDA notifies the State or locality in writing that such assistance is no longer needed...."). The statement appears to place state regulatory actions, including those otherwise in conformance with this Section, subordinate to FDA. AFDO strongly believes that enforcement by the states should **not** be preempted by FDA or USDA, as long as the unsafe eggs are removed expeditiously. AFDO is not aware of any other situations where a federal agency has indicated that regulatory actions by a state or locality are merely providing "assistance" to a federal agency, especially regarding issues that may only involve intrastate commerce. If, on the other hand, FDA is **not** preempting state actions or administrative procedures, and instead is referring to those states and localities specifically using the **federal** authority authorized by this proposal, rather than their own statutory authority, further clarification is needed.

Further, the bureaucratic steps included in the proposed regulations would be imposing a lengthy process on the States, who are duly proud of their expeditious systems for dealing with contaminated and adulterated foods. The complex enforcement process outlined in the proposed regulation will not be used by State and local authorities. AFDO doubts that States will be calling (or for that matter, should have to call) FDA district or regional directors in order to take action to remove adulterated shell eggs from establishments traditionally under their jurisdictions. The diversion process and lengthy process to have adulterated eggs destroyed would be very discouraging to States who already have very streamlined processes. AFDO is *unaware of a single state action brought by a State utilizing the enforcement provisions provided for in the Nutrition Labeling and Education Act*, which should give federal agencies an idea of the magnitude of any proposal to preempt state actions.



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The federal agencies must rely on the States and locals to control shell egg temperature requirements in retail establishments in particular. Again, the ability of states to act against adulterated shell eggs under their own authorities should be made clear in the wording of this Section. Moreover, a 1991 survey conducted by the FDA found that only one state - South Dakota - does not have embargo authority, and authority FDA does not have under the Federal Food, Drug, and Cosmetic Act for foods in domestic commerce. This authority provides the States with the ability to **immediately** remove from commerce any food found to be, or suspected of being, adulterated. Again, as with all legal actions, there are state administrative procedures that provide for due process. The elaborate federal enforcement provisions and the preemptive nature of the proposed regulation will have the net effect of removing State resources from egg regulation at retail. If one considers an average of well over 20,000 retail establishments per state, the FDA would have to provide the resources to regulate retail eggs in more than a million stores in addition to its current inventory of firms. **Consequently, FDA and USDA should utilize partnerships in regard to regulation of shell eggs at retail, rather than preempting state laws and/or duplicating any inspections that may be conducted by state and local jurisdictions.**

Utilization of the Public Health Services Act as proposed in this regulation represents a major change in regulation and enforcement policy with respect to the relationship between federal and state governments. AFDO is concerned about this precedent as it relates to other pathogens in foods when other collaborative and integrated mechanisms are available and historically have been extremely effective. The above referenced State Law Survey identified 23 of the 50 states with automatic adoption of the Code of Federal Regulations (CFR), and most others adopt these requirements by reference (an informal survey in 1995 showed that more than 80 percent of the states adopt the requirements of 21 CFR.). This is why **AFDO has officially requested that FDA adopt relevant sections of the Food Code as regulation.** AFDO believes that having a federal regulation would effectively maintain a lower risk of human illness associated with Se in eggs and at the same time promote uniformity without preempting State and local authority.

AFDO does not believe that FDA has established a strong rationale for preempting the regulation of shell eggs in intrastate commerce. Current data which show a significant reduction in Se isolations do not support and escalating problem or the non-enforcement of retail temperatures by State programs. On the contrary, the data indicate that State and local requirements for the refrigeration of shell eggs, the introduction of new technologies by industry, and consumer education are having a **significant** impact on the number of Se isolates associated with human illness. And, these reductions have been maintained over a three-year period, indicating that the reductions are, in fact, real.



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AFDO is also concerned that **current** regulations for USDA and FDA, when combined, still do not accomplish a "farm to table" strategy for preventing Se-contaminated eggs from reaching the consumer. There have been a number of situations in the past where USDA has requested state assistance in dealing with sanitation issues on the egg farms. AFDO believes that any proposed federal regulations must deal with the entire farm to table continuum, including conditions present on the egg farms.

State and local authorities must be considered a very important component in the strategy to control Se in shell eggs. FDA appears to recognize this with respect to retail inspections, albeit in a cumbersome way (only through enforcement of federal regulations). It is not clear, however, that the entire farm to table strategy encompasses states and locals. It is safe to say that neither FDA nor USDA has the staff to regulate egg safety throughout the continuum. Consequently, in many instances the states will, and must, be called upon to assist or in some cases act as the primary investigative authority. As such, adequate funding for shell egg regulation is essential. Proper traceback investigations and requisite egg sampling, for instance, are quite time-consuming and expensive. Federal agencies must have adequate funding to implement any proposed regulation, whether within the agencies are to pay for state assistance. AFDO hopes that the agencies have anticipated this need in the development of the proposed regulation.

Education. Considering the potential for cross-contamination, and with the hazards that are associated with the consumption of any raw or undercooked source of animal protein, education must play an important role in controlling the growth and spread of Se. The education parameter must be developed in conjunction with current National Food Safety Initiative educational efforts and must target consumers, food service managers, retail store personnel, operators of high risk establishments such as hospitals, nursing homes, and long term care facilities, and egg farm and processing personnel. AFDO believes that an intensive educational campaign is absolutely imperative.

The original advance notice of proposed rulemaking asked if FSIS and FDA should take a more direct role in regulating restaurants, food service operations and retail stores, or should they continue to rely on the Food Code to provide guidance and encourage State and local authorities to adopt and enforce those standards. AFDO is strongly pushing for adoption of the Code by state and local authorities but continues to believe that federal resources should be devoted to areas such as training, inspector certification, risk assessment, program evaluation, imported foods issues, research, development of standards and to provide scientific and technological expertise, where states have adequate inspection programs. States and localities should be trusted to continue already established programs for regulating these segments of the food industry. AFDO also believes that this approach is consistent



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with the concept of the National Integrated Food Safety System, originally advocated by AFDO two years ago, that is currently receiving tremendous focus through the work group process, and which should result in appropriate utilization of all food safety resources to provide consumers with the safest food supply available.

AFDO thanks FDA and FSIS for the opportunity to comment on this important document and looks forward to continuing to work with FDA and FSIS on this issue.

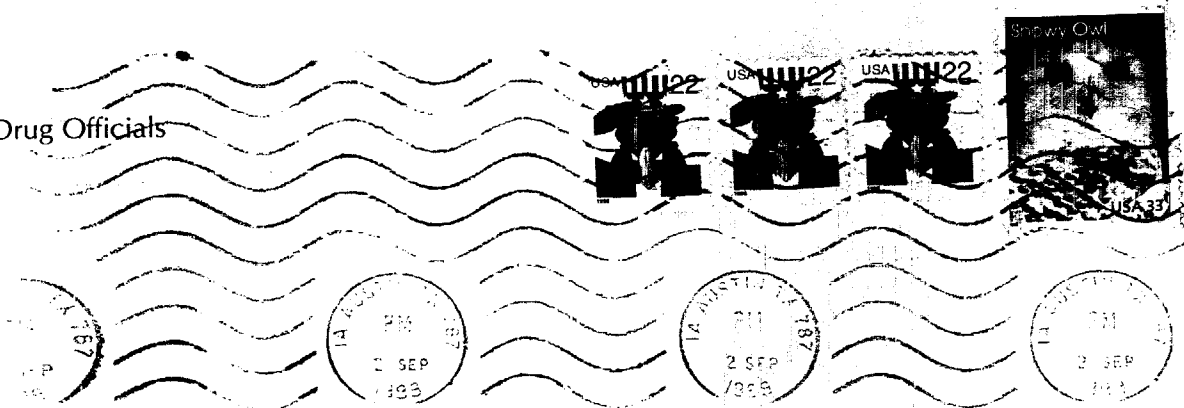
Sincerely,

R. D. (Dan) Sowards, President
Association of Food and Drug Officials

cc: AFDO Board of Directors
AFDO Regional Affiliate Presidents
Denise Rooney, AFDO Executive Director
Betsy Woodward, AFDO Director of Public Policy



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Dockets Mgmt. Branch (HFA-305)
Docket No.s 98N-1230 and 98.045N2
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

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CROSS FILE SHEET

File Number: 98N-1230/ *C480*

See File Number: 97P-0197/ *C481*

96P-0418/ *C480*